DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
San Juan District
Compliance Branch
466 Fernandez Juncos Ave.
San Juan, PR 00901-3223

Telephone: 787-474-9547
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August 27, 2003

WARNING LETTER
SJN-03-13

Certified Mail
Return Receipt Requested

Mr. Jaime Fonalleda
President
VTM Manufacturing Corporation/Vaqueria Tres Monjitas, Inc.
P.O. Box 366757
San Juan, Puerto Rico 00936-6757

Dear Mr. Fonalleda:

This letter is in reference to your company's manufacturing and labeling of food products, as documented by our inspection of your firm, located at 215 Federico Costa Street, San Juan, Puerto Rico 00918, on April 8 and 14, 2003. This inspection was conducted to determine your firm's compliance with the Federal Food, Drug and Cosmetic Act (the 'Act') and applicable implementing regulations contained within Title 21 of the Code of Federal Regulations ('CFR').

During the inspection, copies of your labeling were collected for several of your 'Tres Monjitas' products, including 'toronlite,' 'guava piña,' 'kiwi strawberry,' and 'acerola'. Review of your labels found several violations of the Act and of the implementing regulations. You can find copies of the Act and regulations through links in FDA's home page at www.fda.gov.

The violations are as follows:

1. Your product 'toronlite' is misbranded within the meaning of Section 403(a) of the Act, which states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. As directed by Section 201(n) of the Act, in determining whether a firm's labeling is misleading, account is taken of the extent to which the labeling fails to reveal the consequences which may result from use of the article, in light of representations that are made in the labeling. In this case, 'toronlite' contains aspartame, which is composed of the amino acid phenylalanine. Individuals with a condition known as phenylketonuria are unable to metabolize this amino acid, and hence must control their intake of phenylalanine. As specified in 21 CFR 172.804(d)2), the label of any food containing aspartame must include the following statement on the principal display panel or on the information panel: "PHENYLKETONURICS: CONTAINS PHENYLALANINE". This statement must appear in the labeling prominently and conspicuously as compared to other words, in bold type and on a clear contrasting background.

2. The 'toronlite,' 'guava piña,' 'kiwi strawberry,' and 'acerola' products are misbranded under Section 403(i)(1) of the Act in that the labels fail to declare the common or usual name of the foods. As specified in 21 CFR 102.33, the common or usual name of a beverage that contains less than 100 percent and more than 0 percent fruit juice must be a descriptive name, and where the common or usual name uses the word 'juice', it must include a qualifying term, such as 'beverage', 'cocktail', or 'drink', appropriate to advise the consumer that the product is less than 100 percent juice. In addition, if the "artificial flavor" used in the 'guava piña,' 'kiwi strawberry,' and 'acerola' simulates, resembles, or reinforces the characterizing fruit flavors in question, the product must be labeled in accordance with the requirements of 21 CFR 101.22(i)(2) regarding the placement, size and use of the word 'artificial', or the phrase 'artificially flavored'.

The 'toronlite' product is misbranded under Section 403(r)(1)(A) of the Act. The label includes the claim 'lite' but fails to include, in its immediate proximity, the identity of an appropriate reference food and the percent (or fraction) that the calories have been reduced. This information must accompany the nutrient content claim 'lite' in accordance with 21 CFR 101.56(b)(3).

This letter is not intended to be an all-inclusive list of deficiencies in your products and their labels. As a food manufacturer, you are responsible for assuring that all of your products are manufactured and labeled in compliance with the Act and implementing regulations. You should take prompt action to correct the above-referenced violations and to establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice. The Act provides for the seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

We also note that the percent juice declared on the 'guava piña' label does not comply with 21 CFR 101.30, in that the declaration mentions '4% pure de guayaba' and '17% jugo de piña', but fails to list the total percentage of fruit juice.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed within the 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Mr. Carlos A. Medina, Acting Compliance Officer.

Sincerely yours,

Donald J. Voeller
District Director
San Juan District